IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES L.P.
and TCD ROYALTY SUB LP,

Plaintiffs,

v. No. 21-cv-1710-SB

LUPIN INC. and LUPIN LTD.,

Defendants.

Jack B. Blumenfeld, Jeremy A. Tigan, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, Delaware; Andrew J. Cochran, Gerald J. Flattman, Jr., CAHILL GORDON & REINDEL LLP, New York, New York.

Counsel for Plaintiffs

Megan C. Haney, John C. Phillips, Jr., PHILLIPS, MCLAUGHLIN & HALL, P.A., Wilmington, Delaware; Adrianne C. Rose, Joseph T. Jaros, Natasha L. White, William A. Rakoczy, RAKOCZY MOLINO MAZZOCHI SIWIK LLP, Chicago, Illinois.

Counsel for Defendants

MEMORANDUM OPINION

April 7, 2023

BIBAS, *Circuit Judge*, sitting by designation.

Galderma says Lupin infringes some of its drug patents. A few years ago, Galderma won a lawsuit against another company, Sun, for infringing the same patents. Many of the patents' terms were construed in that suit. Galderma now asks me to clarify those constructions. I narrowly clarify one term but decline to disturb the rest.

I. BACKGROUND

A. Factual and procedural background

The drugs at issue treat mainly skin conditions by administering doses of doxycycline. Though doxycycline has long been used for skin treatments, those treatments could be a hassle. Prior administration methods included implants and injections. Pills were preferable but had to be taken twice a day: doxycycline is an antibiotic, so one big dose would risk fungal growth and antibiotic resistance. Yet patients often fail to follow a two-a-day schedule.

To address that problem, Galderma developed one pill that administers two doses. It does so through immediate- and delayed-release portions. For instance, one capsule could contain some amount of the drug that dissolves right away plus another amount coated in a substance that dissolves slowly. Galderma patented its developments.

Though Galderma has several patents and dozens of claims on this one drug, the following claim is representative:

> 1. An oral pharmaceutical composition of doxycycline, which at a once-daily dosage will give steady state blood levels of doxycycline of a minimum of 0.1 µg/ml and a maximum of 1.0 µg/ml, the composition consisting of (i) an immediate release (IR) portion comprising 30 mg doxycycline; (ii) a delayed release (DR) portion comprising 10 mg doxycycline; and optionally, (iii) one or more pharmaceutically acceptable excipients.

U.S. Patent No. 8,206,740 cl. 1.

Sun already construed the terms disputed here: "immediate release" and "portion." *Galderma Lab'ys, L.P. v. Sun Pharm. Indus. Ltd.*, 411 F. Supp. 3d 271, 281, 297 (D. Del. 2019) (Stark, C.J.). Both parties agree with the previous constructions. But Galderma asks me to clarify them while Lupin asks me to leave them alone.

B. Legal standard

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). Claim construction is a matter of law. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325–26 (2015). So "[w]hen the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve that dispute." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008).

A court generally gives the words in a claim "their ordinary and customary meaning," which is the "meaning that [they] would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1312–13 (internal quotation marks omitted). Usually, a court first considers the claim language, then the remaining intrinsic evidence, and then (in limited circumstances) extrinsic evidence. *See Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331–32 (Fed. Cir. 2001).

Intrinsic evidence includes the patent specification, which "is always highly relevant to the claim construction analysis and indeed is often the single best guide to the meaning of a disputed term." *AstraZeneca AB v. Mylan Pharms. Inc.*, 19 F.4th 1325, 1330 (Fed. Cir. 2021) (internal quotation marks omitted). So a court must construe claims consistent with the specification while "avoid[ing] the danger of reading limitations from the specification into the claim." *Phillips*, 415 F.3d at 1323. Plus, "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear

intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (alteration in original).

A court may refer to extrinsic evidence only if it cannot discern the disputed term's ordinary and accustomed meaning from the intrinsic evidence. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996). Although a court may not use extrinsic evidence to contradict the claim language, extrinsic materials "may be helpful to explain scientific principles, the meaning of technical terms, and terms of art that appear in the patent and prosecution history." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996).

Ultimately, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be … the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

II. CONSTRUING "IMMEDIATE RELEASE"

Below are the parties' proposed constructions and the construction I adopt, with changes to *Sun* in bold:

Galderma	Lupin	The Court
A dosage form that is intended to release substantially all of the active ingredient ***in vivo* following oral** administration with no enhanced, delayed, or extended release effect.	A dosage form that is intended to release substantially all of the active ingredient on administration, with no enhanced, delayed, or extended release effect.	A dosage form that is intended to release substantially all of the active ingredient on administration with no enhanced, delayed, or extended release effect, **where "on" includes immediately after, and "release" is a functional limitation referring to a release that alters the subject's steady-state blood level of doxycycline**.

A. Galderma as lexicographer

To start, Lupin says Galderma cannot change this term's previous construction. Lupin argues that *Sun* merely adopted the patent's definition, so Galderma was serving as its "own lexicographer [and it] must be bound by the express definition." *Sinorgchem Co., Shandong v. Int'l Trade Comm'n*, 511 F.3d 1132, 1136 (Fed. Cir. 2007) (internal quotation marks omitted). (A lexicographer is one who defines his patent's terms. *See Vitronics*, 90 F.3d at 1582.)

Yet, in *Sun*, "[n]o one argue[d] that [Galderma] was its own lexicographer." 411 F. Supp. 3d at 305. Instead, the court chose to adopt the specification's description as its construction. And I may "clarify [an] initial construction." *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1334 (Fed. Cir. 2009).

Even if Galderma did act as lexicographer, I can still construe its definition. I simply read the definition in context and give its words their ordinary meanings. Once I do so, the definition is still valid so long as it "adequately divulge[s] a reasonably clear meaning to one of skill in the art." *Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369, 1375 (Fed. Cir. 1999); *cf. K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1365 (Fed. Cir. 1999) ("[A] dispute over the ordinary and accustomed meaning does not imply that such a meaning does not exist.").

So whether Galderma was its own lexicographer or not, I may construe this disputed term.

B. The clarifications

For the term "immediate release," Galderma seeks three clarifications. First, it wants to add "oral." But the patents in suit uniformly refer to an "oral pharmaceutical composition." *See, e.g.*, '740 Patent cl. 1. So I decline to add this redundancy.

Second, Galderma seeks to change "on" to "following." Though I will not substitute the words, I will clarify that "on" does not require instantaneousness; it includes "immediately after." In construing "delayed release," *Sun* held that the drug is released "immediately after oral administration" if "about 75% of active ingredient" is released "within 30 minutes of oral administration." 411 F. Supp. 3d at 306. And *Sun*'s constructions of immediate- and delayed-release *portions* (the terms I construe next) use "upon" and "following" interchangeably. *See id.* at 309. So I simply state the logical implication: if release is "delayed" after thirty minutes, it is "immediate" before then.

Third, Galderma wants to add "*in vivo*." I agree with Lupin that inserting this phrase would be rash. Though I will clarify "release," I will not change the prior construction's language or use "*in vivo*." Instead, I hew closer to the terms in the claim: "release" is a functional limitation referring to a release that alters the subject's steady-state blood level of doxycycline.

This clarification is narrow. And it should be unsurprising: "release" of a drug's active ingredient means releasing that ingredient *to have its intended effect*, not merely release from a capsule. Achieving specified doxycycline blood levels is "the very property that gives [the] [p]roduct its clinical effectiveness." *Sun*, 411 F. Supp. 3d at 311. Indeed, this clarification is reflected in the intrinsic evidence.

Start with the claim. It says the drug's goal is to "give steady state blood levels of doxycycline" within a specified range. '740 Patent cl. 1. It then defines the drug's composition with immediate- and delayed-release portions. Bridging the two halves, "release" is part of the "pharmaceutical" process in which the patient receives a "dosage" to "give steady state blood levels of doxycycline" within the range. *Id.* The clarification here simply makes that clear connection explicit.

The specification confirms this reading. The first sentence of the "Summary of the Invention" provides:

> The present invention is in its broadest sense directed to pharmaceutical compositions of tetracyclines *designed to provide an extended release profile in vivo* of levels of active ingredient that at steady state are high enough to be effective to have a beneficial effect in the treatment of a disease or condition, but not as high as to exert an antibacterial effect. Such pharmaceutical compositions are formulated into dosage forms that can be taken once a day.

'740 Patent col. 2 ll. 21–28 (emphasis added).

The specification refers to this design twice more. *See id.* col. 3 ll. 45–47, col. 5 ll. 41–43. And there are several other references to the connection between dissolution, release, and uptake. *See id.* col. 3 ll. 35–39 ("[I]t is contemplated that the present invention is applicable to other tetracyclines, particularly other tetracyclines that have similar in vivo absorption profiles as doxycycline … in the gastrointestinal tract."), col. 4 ll. 13–15, col. 7 ll. 47–49, col. 8 ll. 9–14; *cf. Shire Lab'ys, Inc. v. IMPAX Lab'ys, Inc.*, 2005 WL 319983, at *1 (D. Del. Feb. 9, 2005) (construing "immediate release upon oral administration" in a similar patent to mean "the dose of drug is released *and absorbed* without delay after administration" (emphasis added)).

Lupin resists any clarification. Its core concern is that the patent describes only *in vitro* testing, so adding the undefined phrase "*in vivo*" would "lead to mischief." D.I. 97 at 23:15–17. My construction sticking to the claim terms should allay that concern. Yet Lupin's focus on *in vitro* testing is incomplete. True, the drug is generally tested in a petri dish, not a patient. But that *in vitro* testing is used to model *in vivo* behavior. *See* D.I. 34-1 at 605–07. The patents reflect this understanding, referring to computer models and simulated blood-concentration profiles. '740 Patent col. 3 ll. 7–12, 20 & fig. 4. Indeed, the only time "*in vitro*" appears in the specification, "*in vivo*" is in the same sentence:

> The ratio between the immediate-release portion, or component, and the delayed-release portion, or component, can be used to adjust the in vitro drug release profile and in vivo blood concentration profile. By providing such a drug release profile, the compositions eliminate the need for a second dose for the day.

Id. col. 5 ll. 31–36.

This is not to say that *in vitro* testing is insufficient to show how the drug works. That is a question for infringement. As for claim construction, I reach an unsurprising conclusion: a term in a drug patent refers to the drug's effect on the patient.

III. CONSTRUING "PORTION"

Below are the proposed and final constructions, again with changes to *Sun* in bold:

	Galderma	Lupin	The Court
IR Portion	A functional limitation meaning "any part of the claimed composition that releases drug immediately upon administration, with no enhanced, delayed or extended release effect" **(i.e., where "any part" may refer to the chemical release, and does not require physically or structurally discrete parts and includes a combination of one or more parts of the dosage form as a whole).**	A functional limitation meaning "any part of the claimed composition that releases drug immediately upon administration, with no enhanced, delayed or extended release effect."	A functional limitation meaning "any part of the claimed composition that releases drug immediately upon administration, with no enhanced, delayed or extended release effect."
DR Portion	A functional limitation meaning "any part of the claimed composition that delays release of a drug until a time other than immediately following oral administration, e.g., through coating, uncoated matrix, or other impediment to delay release" **(i.e., where "any part" may refer to the chemical release, and does not require physically or structurally discrete parts and includes a combination of one or more parts of the dosage form as a whole).**	A functional limitation meaning "any part of the claimed composition that delays release of a drug until a time other than immediately following oral administration, e.g., through coating, uncoated matrix, or other impediment to delay release."	A functional limitation meaning "any part of the claimed composition that delays release of a drug until a time other than immediately following oral administration, e.g., through coating, uncoated matrix, or other impediment to delay release."

Galderma next wants to clarify the previous construction of "portion," as used in "immediate release portion" and "delayed release portion." In its brief, Galderma proposed a three-part clarification of "any part," wanting to clarify that it (1) "may refer to the chemical release," (2) "does not require physically or structurally discrete parts," and (3) "includes a combination of one or more parts of the dosage form as a whole." D.I. 45 at 35. At the hearing, after (mostly) getting what it wanted in construing

"immediate release," Galderma gave up on part (1) and the word "physically" in part (2). D.I. 97 at 31:12–32:24. But it continued to seek the rest of parts (2) and (3).

I will not accept either. There is simply no "actual dispute regarding the proper scope of the[] claims." *O2 Micro Int'l Ltd.* 521 F.3d at 1360. For part (2), to say that "any part" does not refer to "structurally discrete parts" is merely to restate *Sun*'s holding. *See Sun*, 411 F. Supp. 3d at 305 & n.14 (giving "portion" a "functional" rather than "structural meaning," and noting that a structural discreteness requirement is "nowhere in the intrinsic evidence" (internal quotation marks omitted)).

Part (3) has the same issue. I read Galderma's less-than-clear clarification to say this: even if one "part" of the pill, "as a whole," "includes a combination" of immediate- and delayed-release "dosage form[s]," it is still covered by the term "immediate [or delayed] release portion." That is, even if immediate- and delayed-release portions are intermingled, that combination is not a different "portion." This kind of hybrid "portion" was exactly the issue in *Sun*, where the defendant purported to have a "modified release" portion. *Id.* at 278 ¶ 33. *Sun* refused that framing, instead construing portion to be functional and identifying the immediate- and delayed-release portions of the so-called modified-release portion. *Id.* at 305–10. Again, I decline to clarify what *Sun* already illuminated.

* * * * *

Galderma wants me to add several phrases to prior constructions. But in light of *Sun*, most are redundant or would cause confusion. So I slightly clarify just one of *Sun*'s constructions and leave the rest alone.